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Fax:	571-273-8300	**Date:**	January 25, 2006
Phone:	571-272-0595	**Pages:**	8
Re:	09/960,449	**CC:**	

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•Comments:

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of Holland et al.

Filing Date: September 21, 2001 **Examiner: Ghali, Isis**

Serial No.: 09/960,449 **Art Unit: 1615**

Title: Spray Hydrogel Wound Dressing

Mail Stop AF
Commissioner for Patents
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

The following comments are submitted in response to the Office Action mailed on October 27, 2005 and the Advisory Action mailed on January 19, 2006. This Request for Review is accompanied by a Notice of Appeal and a Credit Card Payment Form for the required payment of $500.00.

The Pending Claims

Claims 1-4, 8-11, 13-17, 21-23, 25, and 27-29 are pending in the application. The claims as pending are listed in the Response to Office Action filed on January 5, 2006.

The Rejections

Claims 1-4, 8-11, 13-17, 21-23, 25, and 27-29 (all of the pending claims) stand rejected under 35 USC 112, first paragraph, for failing to comply with the written description requirement. Claims 1, 2, 8, 9, and 29 stand rejected as being anticipated by U.S. Patent No. 6,007,833 to Chudzik et al. (the '833 patent). Claims 3, 4, 10, 11, 13-17, 21-23, 25, 27, and 28 stand rejected as obvious over the '833 patent in view of U.S. Patent No. 6,179,862 to Sawhney et al. (the '862 patent). The rejections are traversed.

The Claimed Invention

The claimed invention, as recited in independent claim 1, is a hydrogel wound dressing that is formed by spraying a liquid composition onto the wound. The liquid composition includes macromers that crosslink to form the hydrogel when they are sprayed upon the wound. The macromers have a PVA backbone and one or more pendant crosslinkable acrylamide groups

containing olefinically unsaturated groups. Crosslinking is initiated using a crosslinking initiator which is not bound to the macromer or to another polymer.

Independent claim 14 recites a method of making a hydrogel wound dressing directly on the wound by spraying a liquid composition onto the wound which crosslinks into the hydrogel as it is sprayed upon the wound. The liquid composition comprises water soluble PVA macromers having one or more pendant crosslinkable acrylamide groups containing olefinically unsaturated groups and a crosslinking initiator that is not bound to a macromer or another polymer.

Dependent claims 2 and 15 recite that the wound dressing is degradable.

Dependent claims 3, 4, 16, and 17 specify that the composition is delivered using an aerosol or pump spray delivery device. Dependent claims 8, 9, 10, 21, 22, and 23 specify that the composition includes an active agent. Dependent claim 11 specifies that the dressing debrides the wound when it is removed. Dependent claims 13 and 25 specify that the crosslinking is initiator by a redox initiator.

A wound dressing formed by spray application of a composition offers several advantages over application of a liquid composition via syringe, catheter, or dipping. See page 3, lines 1-12 of the specification. Spray delivery can increase the penetration of the polymer into the wound area thereby potentially making the delivery of active ingredients more efficient. Penetration of the polymer into the wound bed may also aid in debridement of the wound during dressing changes to accelerate the wound healing process. With spray delivery of an in situ polymerizing polymer, a thin coating can be achieved with excellent coverage of the treated area.

The Written Description Rejection

The claims state that the composition includes a "crosslinking initiator that is not bound to a macromer or another polymer". The Examiner believes that this element is not sufficiently taught by the specification.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). (MPEP 2163).

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The term "initiator" is used in the specification on page 9, lines 22 and 25 (referring to a photoinitiator); page 17, line13 (referring to a redox initiator); page 19, line 1 (referring to a borate initiator); and page 20, line 2 (again referring to a photoinitiator).

Use of the photoinitator Irgacure is discussed on page 9, lines 21-26 and in Example 13 and it is clear that the initiator is not bound to the macromer itself, or to another polymer. On page 9, a redox couple initiator is discussed- wherein one solution contains a reducing agent such as a ferrous salt and another solution contains an oxidizing agent such as hydrogen peroxide. Obviously neither initiator is bound to a macromer or other polymer. See also Examples 1-8 and 14-17. The use of borate as an initiator is discussed on page 19 and Examples 9-11. Again, it is clear that the borate initiator is not bound to the macromer itself, or to another polymer. In fact, nowhere in the specification is a bound initiator discussed at all.

Accordingly, it is clear that Applicants have disclosed the use of a polymerizing initiator not bound to the macromer or another polymer. The Applicants do not have to delineate each and every unbound initiator that can be used. Nor does the specification need to have a specific statement that the initiators are unbound to satisfy this requirement. Applicants argue that one skilled in the art would understand that the claim element "crosslinking initiator that is not bound to a macromer or another polymer" refers to initiators such as those specifically disclosed.

The rejection of claims 1, 2, 8, 9, and 29 over the '833 patent

The '833 patent teaches a crosslinkable macromer system. The system can be used as a wound dressing. The system includes two or more polymer/macromer-pendant polymerizable groups and one or more polymer/macromer-pendant initiator groups. The Examiner agrees that the "initiator group is present as either a pendant group on a polymerizable macromer, or pendant on separate, non-polymerizable polymer backbone" (See the Office Action of October 27 on page 4). Since Applicants claims are drawn to an unbound initiator (a "crosslinking initiator that is not bound to a macromer or another polymer"), this reference does not teach the claimed invention.

In fact, the '833 patent specifically teaches that free initiators should be avoided as they can present issues of toxicity, efficacy, and solubility (see col. 2, lines 15-20). To this effect, **the initiators are bound to the backbone of either the polymer or macromer**.

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In the Office Actions, the Examiner points to the teaching in the '833 patent at column 6, line 50 that a reductant can be incorporated into the polymer backbone as evidence that the initiator can be separate from the macromer backbone. This argument is illogical. In fact, the '833 patent teaches that the initiator can be separate from the backbone- as in pendant on the polymer but not incorporated into the backbone- but the whole point of the '833 patent is that the initiator is bound to the polymer in some manner- whether in the backbone itself, or pendant from the backbone. The initiator is still bound to the macromer or polymer.

The Examiner states that the '833 patent teaches spray delivery because it does not teach any method of delivery at all ("US '833 teaches the liquid delivery of the composition without excluding or specifying any method of delivery, thus the spraying the [sic] liquid composition into the wound is inclusive in the reference teaching."). In fact, the '833 patent does teach several methods of delivery, none of which are spray delivery- it teaches applying the liquid composition via a catheter (see col. 10, lines 27-29); via syringe (see col. 16, lines 52-59); and via dip coating (see Examples 16 and 17).

The rejection of claims 3, 4, 10, 11, 13-17, 21-23, 25, 27, and 28 over the '833 patent in view of the '862 patent

The '862 patent teaches a method for forming a tissue adherent barrier in situ using a sprayer to deliver crosslinkable fluids. One of the fluids specifically described as suitable in the method is a solution of macromer. However, the only macromer specifically discussed is a PEG-oligolactyl-diacrylate macromer which has a PEG core unit, a polyhydroxy acid extension on each end, and an acrylate end group on each end. PEG has only two hydroxyl groups - at each terminus- to which the crosslinkable acrylates can be fastened (see col. 6, ll. 18-32). The claimed macromers, on the other hand, because they are based on PVA, have crosslinkable groups on pendant chains- chains hanging from the backbone. A tremendous advantage of using PVA rather than PEG is that there are many available hydroxyl groups to which crosslinkable or other groups can be attached, and not just two, as in PEG. Thus, the use of PVA as the backbone of the macromers claimed in the present application offers advantages unexpected and unforeseen by the prior art.

The '862 and '833 patents are cited in combination as rendering the claims obvious. The Examiner argues that the '833 patent teaches the macromers, which is not true, as discussed

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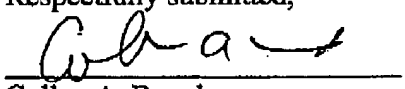
above. The Examiner states that the '833 patent teaches the initiator can be not bound to the macromer. But this is not what Applicants have argued or what they claim. The claims recite an initiator that is "not bound to a macromer or another polymer".

There exists no reason to combine the teachings of the references. In fact, as discussed previously, the '833 patent teaches away from the invention recited in the claims because it specifically teaches using a bound initiator. Moreover, even if the references are combined, the claimed invention does not result. The combined patents do not teach a wound dressing formed by spraying a PVA macromer having one or more pendant crosslinkable groups and using an unbound initiator.

Conclusion

Reconsideration of the claims is respectfully requested.

Respectfully submitted,



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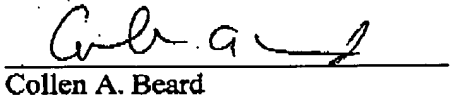

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